510(k) summary

This 510(k) summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter:

IVT Medical Ltd.,
16 Hatidhar St.
Raanana 43665
ISRAEL

SEP 17 2013

Name of the Device:

- Trade name – Vcare α
- Common name - Negative Pressure Wound Therapy (NPWT) device.
- Classification name -, Powered suction pump (21 CFR 878.4780, procode OMP).

Name and address of contact person:

- Dr. Eli M. Orbach
- POB 6718, Efrat 90435, Israel
- Tel:/Fax +972.2.993.2768;
- e-mail: orbach@efratnetworks.com

Predicate Devices: The Vcare α® is substantially equivalent to the V.A.C. Therapy System, manufactured by Kinetic Concepts Inc., subject of k062227.

Indications for Use:

The Vcare α is intended for wound management via application of continual or intermittent negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. It is indicated for management of chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The Vcare α may promote healing by removal of excess exudates, irrigation fluids, and infectious material.

Description of the Device:

The Vcare α® is a Negative Pressure Wound Therapy system that comprises fixed components and disposables. The Vcare α® maintains the functionality of existing devices while enhancing safety. The system has features that optimize the delivery of negative pressure to open wounds. The software requires the user to profile the patient and the system then limits the device's operational parameters to be compatible with the patient profile.

The system incorporates safety features that control the system to prevent risk to the patient. The sensors and controls monitor and maintain target pressure and alarms, as needed, to help assure that target pressure is maintained and constant therapy is

delivered. The safety features of the system include additional alarms, such as those that signal for possible bleeding, tubing blockage, a full or missing collection canister, inactive therapy, low battery and leaks in the seal of the dressing.

Device Comparison Table

Category	Features	Vcare α®	KCI
Safety Features	Operational program according to risk of bleeding	The treating physician pre-determines the risk of bleeding to the wound	None
	Software control of user operation	Hazardous or undesired operation is limited according to risk of bleeding determination by the physician. The software pre-limits the vacuum level range, maximal flow and alarms.	None
	Bleeding Detection	A unique feature that monitors the filling rate of the canister and detects active bleeding. Preset to 100, 200 or 300 cc/hr (default 100 cc/hour that can only be changed if the risk of bleeding is low)	None
	Bleeding Control	Stops and alarms when flow exceeds the pre-determined flow rate (default is 100 cc/hour)	Stops when canister is filled
	Audio & visual alarms	Yes	Yes
	Signals	"check for bleeding", "canister over-flow", "Low vacuum", "High vacuum"	Yes, but not for bleeding
Canister Volume	Canister Volume Availability	800ml canister with software restriction to maximal volume of 700ml	800 ml
Overflow Protection Features	Overflow Hydrogel pack solidifier for wound exudates	Yes	Yes
Negative Pressure Settings	Negative Pressure Setting Range	Wide range of negative pressure levels (30-200 mm Hg) for treatment of diverse wound types, limited according to the	Yes (40-200)

		risk of bleeding and according to clinical guidelines	
	Pressure Settings	Pre-set recommended values with the ability to set to any value linearly within the range.	Ability to set to values only in 25 mm increments
Versatile Operational Modes	power supply	Unique variable 100-240V AC through AC/DC power adapter with output voltage of 15V, or battery operation (12V). Automatic switching between power adapter and battery when the power adapter is disconnected or connected to the device, to allow continuous treatment.	Battery and Power Line
	Various vacuum intensities	Select different pump intensities to accommodate small and large, low and high flow wounds	Yes
	Work Modes	Cyclic-Continuous, Continuous and intermittent operational working modes	Continuous and intermittent operational work modes
Pump Flow Capacity	Flow Limited by internal motor capacity	20 L/Min	Information not available
External Vacuum Attachment	Dual Operation Mode of Internal Pump and Connection With External Vacuum	Vcare α controls external vacuum source according to device settings and resulting in extended motor life. External Pump evacuation flow may be exceeded as needed.	Non - Compatible
Motor Life expectancy	Extension of Motor life	Extremely extended under wall suction operation	Limited by internal motor life expectancy (Roughly 1000 hours)
Operation under minor leak	Operation under minor leak	The Vcare alpha can operate under minor leaks when it is difficult or impossible to fully seal the wound	Pre-determined cessation of operation

Sponge	Sealed outer layer	Yes	No
	Color	Off-white sponge for early and easy detection of bleeding,	Black Sponge
	Soft and flexible Sponge	Easy to conform, allows formation of bridging conduit	Thick and hard to conform
Sealing Drape		Drape stripes are applied only to the sponge margins and are adjusted to sponge size.	Drape sheets that need to be cut and fit to cover and seal sponge.

Review of the comparison table leads demonstrates that any differences in technological characteristics from the predicate device raise no new types of safety or effectiveness questions and leads to the conclusion that the comparison supports substantial equivalence.

August 1, 2013

Date

Dr. Moris Topaz, CEO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

September 17, 2013

IVT Medical Ltd.
% Dr. Eli M. Orbach
P.O. Box 6718
Efrat 90435, Israel

Re: K121817
Trade/Device Name: The Veare *a*
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: August 01, 2013
Received: August 26, 2013

Dear Dr. Orbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121817

Device Name: Vcare α

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K121817